

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte PHILIPPE CROS, ABDELHAMID ELAISSARI,
CLAUDE MABILAT, CHRISTIAN PICHOT,
MARC RODRIGUE, and LISE SANTORO

Appeal No. 2001-0499
Application No. 08/945,731

HEARD: March 19, 2002

MAILED

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Before WILLIAM F. SMITH, SCHEINER, and GREEN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

VACATUR AND REMAND TO EXAMINER

Having considered the record and listening to oral argument, we conclude that this case is not in condition for a decision on appeal. Accordingly, we vacate the examiner's rejection and remand the application for the examiner to take appropriate action.

Claim 3 is representative of the subject matter on appeal reads as follows:

3. Process for the isolation in aqueous phase of a nucleic material present in a sample by adsorption of said nucleic material onto a particulate support, comprising:

(a) providing an adsorption reagent comprising a sol consisting of an aqueous continuous phase and a discontinuous phase of the particulate support, which comprises a functionalized, particulate polymer, said polymer being obtained by polymerization of (1) a first water-soluble monomer of acrylamide or of an acrylamide derivative, (2) at least one cross-linking agent and (3) at least a second cationic and water-soluble functional monomer, said polymer having a predetermined lower critical solubility temperature (LCST) which is between 25 and 45°C,

(b) bringing into contact the adsorption reagent with the sample containing the nucleic material to absorb the nucleic material to the particulate support,

wherein, in said contacting step (b), the reaction medium has:

- an ionic strength at most equal to 10^{-2} M,
- a pH at most equal to 7, and
- a temperature less than the LCST of the polymer,

(c) optionally observing that the adsorption has taken place, and

(d) separating the discontinuous phase from the continuous phase.

The references relied upon by the examiner are:

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|------------------------------|------------|---------------|
| Hoffman et al. (Hoffman) | 5,912,032 | Mar. 27, 1990 |
| Kausch et al. (Kausch) | 5,508,164 | Apr. 16, 1996 |
| Kawaguchi et al. (Kawaguchi) | 5,122,600 | Jun. 16, 1992 |
| Itoh et al. (Itoh) | EP 161,881 | Nov. 21, 1985 |

Claims 1 through 3 and 5 through 23 stand rejected under 35 U.S.C. § 103(a).

As evidence of obviousness, the examiner relies upon Itoh, Hoffman, Kausch, and Kawaguchi.

VACATUR

We begin with the proposition that this board serves as a board of review, not as a de novo examination tribunal. 35 U.S.C. § 6(b). Review of the examiner's position in this appeal is difficult since the examiner has not applied the teachings of the cited prior art against the requirements of any individual claim on appeal.

At page 4 of the Examiner's Answer, the examiner refers the reader to Paper No. 10 for a statement of the rejection. Paper No. 10 is an Advisory Action entered on

November 10, 1999. Therein, the examiner explains why the claims pending at that time were considered to be unpatentable under 35 U.S.C. § 103(a) on the basis of Itoh, Hoffman, Kausch, and Kawaguchi. The explanation is unusual in that it is a blend of a statement of a rejection and an answer to arguments. Be that as it may, the explanation is difficult to review since the examiner does not refer to any individual claim on appeal but, rather, couches the explanation in terms of "the claims" or "the instant invention." As a result, we have a very general statement as to what purportedly would have been obvious to one of ordinary skill in the art but not a specific statement as to why claim 3, the broadest claim pending, would have been obvious to one of ordinary skill in the art.

While the examiner does point to specific disclosures of the four documents in the explanation, at crucial points in the examiner's analysis we are left with surmise and conjecture. For example, the examiner states in the paragraph bridging pages 4-5 of Paper No. 10:

A further reading of Itoh et al. at page 47, lines 6-24 reveals a teaching of the general mechanism of action of the polymer. Stating that high molecular weight substances are retained at low temperatures and released at high temperatures. While Itoh et al. did not contemplate nucleic acids to be treated in this manner, it is clear that an understanding of the general mechanism of action of the polymer is sufficient to teach one of skill in the art how to use the polymer.

Another example appears at page 5 of Paper No. 10 where the examiner states that "the general teachings of Itoh ... are sufficient to teach one of skill in the art how to use the polymer"

The vagueness and lack of specificity of the examiner's position is perhaps pointed up most succinctly in the paragraph bridging pages 6-7 of Paper No. 10 which reads as follows:

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Itoh et al., Hoffman et al., Kawaguchi et al. and Kausch et al. to produce the instant invention because Itoh et al., Hoffman et al., Kawaguchi et al. and Kausch et al. were all using acrylamide polymers with a copolymer which would adsorb and desorb nucleic acids and proteins. Itoh et al. taught the use of the acrylamide polymer in bead form, and coated onto solid supports. Hoffman et al. taught the adsorption of nucleic acid in a low ionic strength buffer and the desorption of the nucleic acid in a high ionic strength buffer. Kawaguchi et al. and Kausch et al. taught the coating of polyacrylamide onto solid bead supports, and Kausch et al. taught the polyacrylamide coated beads which comprised a magnetic compound to facilitate the isolation of the bead with the bound DNA in a magnetic field.

That paragraph begs the question what is the "instant invention?" Patentability is determined based upon the individual claims pending in an application, not an "invention." In other words, examiners do not examine the "invention" to determine whether an applicant is entitled to a patent under Title 35 of the United States Code. Rather, the examination is based on the individual claims appearing in the patent application. The lack of specificity in the examiner's statement is also highlighted in this paragraph in that Kawaguchi and Kausch are relied upon to teach coating of polyacrylamide onto solid bead supports and polyacrylamide coated beads comprised of a magnetic compound respectively. Neither of these requirements is found in claim 3 on appeal.

An example of an unsupported assertion made by the examiner is found at page 4 of Paper No. 10 where the examiner states:

While Itoh et al. did not specifically teach the use of a low ionic strength binding buffer nor the increased ionic strength of an eluting buffer, one of ordinary skill in the art would know that the use of an affinity matrix would require the use of elements such as a low ionic strength binding buffer and an increased ionic strength buffer to elute the bound nucleic material.

Another example appears in the paragraph bridging pages 4-5 of Paper No. 10 as follows:

A further reading of Itoh et al. at page 47, lines 6-24 reveals a teaching of the general mechanism of action of the polymer. Stating that high molecular weight substances are retained at low temperatures and released at high temperatures. While Itoh et al. did not contemplate nucleic acids to be treated in this manner, it is clear that an understanding of the general mechanism of action of the polymer is sufficient to teach one of skill in the art how to use the polymer.

It is clear from reading Itoh that it is relevant in determining the patentability of claim 3 on appeal. However, in critical passages, Itoh contradicts or is opposite that which is required by claim 3 on appeal. For example, claim 3 requires that the nucleic material be absorbed at a lower temperature and be released at a higher temperature. In the one mention of nucleic acids in Itoh, the reference states that "these compounds may be held at high temperatures and released at low temperatures." Itoh, page 44, line 13- page 45, line 13. However, as observed by examiner and appellants, Itoh goes on to state at page 47, lines 19-24 that:

Where materials, which are to be released, are held in gel-like polymers, they are held at low temperatures as the gel-like polymers are swollen at the low temperatures and are released at high temperatures as the gel-like polymers are shrunk at the high temperatures.

It may be that a person of ordinary skill in this art reading Itoh in its entirety would reasonably conclude that regardless of the other teachings in the document, when gel-like polymers are used according to that invention, they absorb at a low temperature and release at a high temperature similar to the polymer sol required by claim 3 on appeal. If so, then one of ordinary skill in the art would understand that the specific teaching in regard to absorption and release of nucleic acids at page 45 of the document, which is opposite that required by claim 3 on appeal would apply only when

non-gel-like polymers are used in Itoh. We do not have such a finding from the examiner.

As a final example of the difficulty of reviewing the examiner's position, we point to the claim requirement that the polymer contain a second, cationic monomer. The examiner states at page 8 of Paper No. 10 that Itoh teaches the use of cationic monomers at page 24, lines 11-21. However, that passage of Itoh is directed to homopolymers and copolymers which contain carboxylic acid groups. It is not readily seen how those polymers would be considered cationic. However, that is not to say Itoh does not specifically address the issue. Itoh states at page 50 that a "more selective holding and release" can occur if an ionic monomer, such as a cationic monomer is used in the polymer. If nucleic acids are anionic in nature, this latter passage from Itoh may supply the requisite reason, suggestion, or motivation to use a cationic, gel copolymer as otherwise described in Itoh to separate nucleic acids by absorbing at a low temperature and releasing at a high temperature. Again, we do not have such findings and conclusions from the examiner.

The Court of Appeals for the Federal Circuit reviews board decisions. 35 U.S.C. § 144. The court discussed their statutory duty of review in Gechter v. Davidson, 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997). In considering the issue, the court stated "the statute's mandate to 'review' implies inherent power in this court to require that the Board's decision be capable of review." Id., F.3d at 1457, 43 USPQ2d at 1033. The court observed "Necessary findings must be expressed with sufficient particularity to enable our court, without resort to speculation, to understand the reasoning of the Board, and to determine whether it applied the law correctly and whether the evidence

supported the underlying and ultimate fact findings." Id. What the Federal Circuit rightfully expects from the Board, the Board expects from the examiner.

Under these circumstances, it is appropriate to vacate the rejection and return the case to the jurisdiction of the examiner to reconsider the patentability of the claims.

REMAND

Upon return of the application the examiner should take a step back and reassess the patentability of the claims. The reassessment should take place on a claim-by-claim basis beginning with claim 3. If the examiner believes that claim 3 is unpatentable on the basis of Itoh and/or other relevant prior art, he should state the facts and reasons used in support with particularity.


There is other evidence of record which may be relevant in putting Itoh in proper factual context to the extent it describes the separation of nucleic material. We refer to European Patent Application No. 0 501 301 A2, Mori, of record. Mori describes an electrophoretic gel comprising at least one cross-linked temperature-responsive polymeric compound having an LCST used to separate nucleic acids. As described by Mori, the acrylamide based gels of that reference are used to absorb nucleic acids at low temperatures and release the absorbed material at high temperatures. See, e.g., column 6, lines 31-54. This information may provide evidence that Itoh's disclosure that gel polymers absorb at a low temperature and release at a high temperature does apply to nucleic acids and thus provides an answer to appellants' argument that Itoh is to be read restrictively as only teaching absorbing nucleic acids at high temperature and releasing at low temperatures.

To the extent Itoh and other relevant references teach that absorption and release of valuable substances using LCST polymers depends on temperature, pH and ionic strength¹ but do not specifically teach the specific parameters required by the claims on appeal, the examiner should determine if such parameters are result effective variables. If so, optimization of such values may have been obvious. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980).

FUTURE PROCEEDINGS

We state that we are not authorizing a supplemental examiner's answer under 37 CFR § 1.193(b)(1).

VACATED; REMANDED


William F. Smith
Administrative Patent Judge


Toni R. Scheiner
Administrative Patent Judge


Lora M. Green
Administrative Patent Judge

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¹ See Hoffman, column 1, lines 25-39 (LCST polymers undergo phase separation in response to change in solution pH, ionic strength or temperature.).

Appeal No. 2001-0499
Application No. 08/945,731

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Oliff & Berridge
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Application Serial Number 08/945731

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| <u>Docket Personnel I</u> | | |
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DESIGNATION OF PANEL

Pursuant to (1) the Commissioner's authority to designate the members of the Board of Patent Appeals and Interferences to hear cases before the Board (35 U.S.C. 7(b)), and (2) Commissioner Lehman's memorandum dated May 1, 1994 (delegating to the Chief Administrative Patent Judge the responsibility of designating members to hear cases before the Board), it is ORDERED that the panel of the Board of Patent Appeals and Interferences designated to hear this case shall consist of the following members of the Board:

☐ On Brief ☒ Heard ☐ Redesignation ☐ Expanded Panel,
see addendum.

1. Judge LC Smith
2. Judge Scheiner
3. Judge (LHMC) Green

Bruce H Stoner Jr
BRUCE H. STONER, JR.

Chief Administrative Patent Judge

Date of Hearing: March 19, 2002

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